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Title page

Intervention Integrity in Mindfulness-Based Research: strengthening a key aspect of methodological rigor

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Introduction

Assessing program fidelity or intervention integrity is an important methodological consideration in clinical and educational research. This critical variable influences the degree to which outcomes can be attributed to the program, and so is a key element of methodological rigor. The body of scientific evidence supporting Mindfulness-Based Programs (MBPs) has been criticized for being of poor methodological quality in the early growth of the curve of expansion [1,2] and more recently [3,4]. Goldberg et al conducted a systematic review which examined the extent to which mindfulness research has demonstrated increased rigor over the past 16 years regarding six methodological features that have been highlighted as areas for improvement [5]. These features are: the use of active control conditions, larger sample sizes, longer follow-up assessment, treatment fidelity assessment and reporting of instructor training, and intent-to-treat. Overall the findings of the study suggested only modest adoption of the recommendations for methodological improvement voiced repeatedly in the literature. In this paper the focus is on the treatment fidelity and reporting of instructor training element in this list. Specifically what the literature is telling us now about how this issue is being addressed, what the challenges are in strengthening rigor in this area, and recommendations for next steps.

First some clarification of terms and the territory. Treatment fidelity and intervention integrity are used interchangeably in the literature to denote the level to which a particular intervention or program is delivered as was intended by the developers. In order to determine this there needs to be systems to verify the level of faithfulness to the model. The issue is important in research contexts because without these checks it is not possible to determine whether outcomes are a result of the intervention or the way it was applied/delivered. It is also important in practice contexts, to ensure that in the transition from research to routine delivery, the potency of the intervention is maintained. The focus for this paper however is the implementation of intervention integrity checks in research contexts.

There are three elements to intervention integrity – adherence, differentiation and competence. Adherence is the degree to which the practitioner includes the prescribed content of the curriculum/program, whilst differentiation checks whether proscribed elements are included, and that the distinctive features of the intervention are maintained. Competence is the practitioner's level of skill and judgement in delivering the intervention

[6]. Each component of integrity captures a unique aspect of intervention integrity that together, and/or in isolation, may be responsible for therapeutic change or lack thereof [7]. Meaningful fidelity checks enable nuanced analysis of the potential reasons for particular study outcomes. For example, it becomes possible to analyse whether outcomes may have been influenced by differing levels and sorts of teacher training, adherence to good practice norms, or whether specific domains of teacher competence are important for particular outcomes [8].

How is intervention integrity being addressed now in the MBP field?

In their study investigating whether methodological rigor had improved over the last 16 years, Goldberg et al analysed 142 randomised controlled trials [5]. In the element investigating intervention integrity they examined in each of these studies whether treatment fidelity was assessed, and whether the training of the teachers was reported. Less than half of the studies (32.39%) assessed and reported treatment fidelity. Teacher mindfulness training was reported in a larger sample (73.24%), but this number was smaller when asking whether the teacher had received training in the specific MBP being researched (63.38%). A marginally significant increase over time (since 2002) in the reporting of fidelity assessments was found. They did not analyse the quality of the reporting. There is concern in the field that researchers employ the labels of standard MBPs (e.g. Mindfulness-Based Stress Reduction and Mindfulness-Based Cognitive Therapy), without full adhering to the publicised curriculum guides [9].

The MBP researcher needs frameworks and methodologies in order to integrate intervention integrity checks into the research journey. In a previous paper we outline and recommend the use of the “Template for Intervention Description and Replication” (TIDieR) guidelines [10], for addressing and reporting on intervention integrity during the various phases of the conduct of research, and provide specific suggestions about how to implement these guidelines when reporting MBP studies [11]. TIDieR guidelines provide a detailed set of recommendations for how to report interventions so that adequate information is provided to allow replication. The TIDieR guidelines provide an important roadmap for improving reporting on the intervention component of MBP trials in general, and how intervention fidelity assessment was addressed. TIDieR guidelines unpack item 5 of the CONSORT guidelines (Consolidated Standards of Reporting Trials), an important set of

good practices for reporting clinical trials [12]. Item 5, involves describing the: “interventions for each group with sufficient detail to allow replication, including how and when they were actually administered”. Table 1 offers a summary of the TIDieR guidelines as applied in the MBP research context. See Crane & Hecht [11] for a detailed description of the practical application of these guidelines.

Table 1 here

Table 1: The Template for Intervention Description and Replication (TiDieR) checklist: information to include when describing an intervention, with additional guidance (in italics) on applications to MBP research. Adapted from Table 1 in Hoffman et al. [10] and Crane & Hecht [11].

Item Number	Item
Brief name	Provide the name or a phrase that describes the intervention and <i>reference to the most recent curriculum guide – i.e. MBSR [13]</i>
Why	Describe any rationale, theory, or goal of the elements essential to the intervention. <i>In addition to referencing published literature on this issue, theoretical rationales are needed for any adaptations, or tailoring to a particular population or context.</i>
What	<p>Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL). <i>For example, written course materials and guided mindfulness meditation practices.</i></p> <p>Procedures: Describe each of the procedures, activities, and/or processes used in the intervention. <i>If using a published MBP curriculum guide this is not needed - only include descriptions of adaptations. Detail in full if delivering a new MBP.</i></p>
Whom provided	For each category of intervention provider, describe their expertise, background, and any specific training given. <i>Describe (1) what MBP teacher training has been undertaken by trial teachers, (2) how they adhere to ongoing MBP Good Practice Guidelines such as on-going practice [14,15], and (3) measures of teacher competence that were used to select trial teachers</i>

How	
	Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention, and whether it was provided individually or in a group. <i>If following a standard MBP curriculum guide this is not required – only detail deviations/adaptations from standard protocols, or if a new curriculum, detail in full, including delivery method (i.e. in person teacher-led group sessions; digital delivery etc).</i>
Where	
	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.
When and How Much	
	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose. <i>If following a standard MBP curriculum guide this is not required – only detail deviations/adaptations from standard protocols, or give full details of new MBPs.</i>
Tailoring	
	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how. <i>Describe how individual needs/vulnerabilities of MBP group participants were handled by the trial teacher(s), and whether any steps such as individualized additional meetings with the teacher were used to address issues that varied by participant.</i>
Modifications	
	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)
How well	

.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them. <i>Describe whether an MBP fidelity tool was used to assess intervention delivery via reviews of recorded sessions, by whom and how. Describe the rationales for the choices made.</i>
.	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned. <i>Detail the assessed level of MBP teaching competence, adherence and differentiation in the results section of the paper.</i>

Items 11 and 12 of the TIDieR guidelines rely on having systems to check levels of program and teacher adherence, differentiation and competence. This is generally assessed observationally by a trained assessor who views and rates sessions via an audio-visual recording. Assessment units can be a whole programme or individual sessions. Future research could also include analysis of the effectiveness of indirect methods of assessment used alongside observational measures, such as MBP teacher and/or participant assessment of teaching skill.

Currently, three tools for assessing intervention integrity in the MBP field have been developed and researched to assess adherence and/or teaching competence: the Mindfulness-Based Cognitive Therapy-Adherence Scale (MBCT-AS) [16] the Mindfulness-Based Relapse Prevention-Adherence and Competence Scale (MBRP-AC) [17], and the Mindfulness-Based Interventions: Teaching Assessment Criteria (MBI:TAC) [18]. Further research is needed on these tools to better define their interrater reliability and their ability to measure elements of teaching competence that are important for participant outcomes. In Table 2 we summarize the methodologies currently available to the MBP researcher for assessing intervention integrity, and the research on them. For further details on the empirical status of each method see Crane & Hecht [11], but in brief:

MBCT-AS: This tool only focuses on adherence, and only on the MBCT program. Inter-rater reliability was good, but was assessed with only 3 raters rating 16 audiotapes so has not been fully established.

MBRP-AC: This tool addresses both competence and adherence, but just with the MBRP program. Inter-rater reliability was assessed over a substantial number of sessions (44), but with only by 2 raters which is not sufficient be definitive. The results were modest – the lower range of moderate reliability.

MBI:TAC: This tool addresses both competence and adherence, with MBCT and MBSR – and is now being adapted to other MBPs. The preliminary evaluations of inter-rater reliability and validity are encouraging, but there are important limitations of this initial validation work. Although assessments of 43 teachers were rated, only two assessments of reliability were used which limits precision.

Finally, the predictive validity of all these tools in terms of the relationship between teacher skill and participant outcome has barely begun to be assessed. The exception to this is an

investigation of the MBI:TAC and its links to participant outcome conducted by Huijbers et al., 2017 (see table 2)

[Table 2 here]

Table 2: Tools for assessing MBP intervention integrity. Adapted from Crane & Hecht [11]

Tool	Target MBP	Which aspects of intervention integrity it assesses	Publications	Focus of research
Mindfulness-Based Cognitive Therapy Adherence scale (MBCT-AS)	MBCT	Adherence	Segal et al., 2017 [16]	Initial evaluation of psychometric properties
			Prowse, Meadows, & Enticott, 2015 [19]	Research on the tool embedded within an MBCT trial
Mindfulness-Based Relapse Prevention Adherence and Competence Scale (MBRP-AC)	MBRP	Adherence, competence	Chawla et al., 2010 [17]	Psychometric properties
			Zgierska et al., 2017 [20]	Research on tool embedded within an MBRP trial
Mindfulness-Based Interventions: Teaching Assessment Criteria (MBI:TAC)	MBSR, MBCT Adaptation made for Mindfulness in Schools program	Adherence, differentiation, competence	Crane et al., 2013 [18]	Initial evaluation of psychometric properties
			Huijbers et al., 2017 [21]	Analysis of links between participant outcome and teacher competence as

assessed by

MBI:TAC

Current methodologies for assessing intervention integrity in the MBP field are at an early stage in their development. Research is needed to build empirical understanding, and development work is needed to support the process of implementation of systems for fidelity checking. See [Crane & Kuyken, 2018](#) this issue for analysis of the current status of the development of the Mindfulness-Based Interventions: Teaching Assessment Criteria (MBI:TAC) [18,22]

Challenges in strengthening rigor in assessing intervention integrity

Intervention integrity is a challenging area for MBP researchers to address in amongst the multiple other complexities of conducting research. Here we outline some key challenges:

1. *Access to the appropriate tool for the job:* It is challenging to create fidelity measurement methods that are both effective (scientifically validated) and efficient (feasible and useful in research and routine delivery) [23]. As stated above, there is research and development work needed in this area. The MBI:TAC for example was developed for one context (Master's program delivery), and is being implemented in other contexts but adaptation may enable more fine-tuned tailoring to the needs of a particular context. Furthermore, MBPs are complex interventions so it is a particularly challenging context within which to develop effective fidelity assessment tools. A key emphasis within MBP teacher training and program delivery is the importance of embodied communication of mindfulness by the teacher, which draws on the teacher's personal practice of mindfulness. This strong reliance on a certain sort of inner work within the teacher to enable effective teaching practice is challenging to assess observationally. The task is to develop tools that assess how this inner work becomes tangible within the MBP teaching space – but doing this in ways that honour the subtleties (which are likely to be critical factors in enabling participant change) is challenging.
2. *Access to resources:* In practice, the level of engagement with recommended fidelity assessment strategies will depend on resources (time, money, assessor training). It does need investment in these resources to do it well. Increasingly though, attention in this area will be a requirement for publication, so it is important to factor this in when seeking funding for research.

3. *Multiple program forms*: If researchers are investigating an existing published MBP, it is important that there are clear checks in place so that this piece of research can be compared to other trials on this intervention. Many researchers are however investigating newly developed/adapted MBPs. They therefore have to do considerably more ground work to ensure that the program is clearly described in publications so that it can be replicated.

Recommendations for strengthening rigor in assessing interventions integrity

1. *Conduct research and development work on existing systems for assessing MBP intervention integrity*: Whilst current developments offer a foundation for next steps, it is also clear that the methodologies to assess teaching integrity within the MBP field are at an emergent stage in their development. More work is needed to assess their psychometric properties; to better define their interrater reliability and their ability to measure the elements of teaching competence that are important for participant outcomes; and to ease their implementation in research and practice contexts by developing training routes, resources and materials for users.
2. *Implement the systems already developed*: Whilst acknowledging that current integrity methodologies are a work in progress it is important for researchers to use existing systems for assessing intervention integrity. This will ensure that their research is as robust as it can be at this point in time on this issue, and that the collected experience of researchers using these systems and disseminating results will inform forward development.
3. *Implement the adapted TIDieR guidelines*: the TIDIER guidelines supporting engagement with Item 5 of the CONSORT guidelines for good conduct in clinical trials offers a helpful framework for researchers. For ensuring completeness of reporting of the intervention(s) within their study it is recommend that researchers of MBPs use the TIDieR framework and supporting resources; and that the Mindfulness journal supports this implementation process by adopting them within the editorial requirements for the journal.
4. *Reviewers should be alert to intervention integrity*: Peer reviewers and journal editors should also bring the issue of reporting of intervention integrity onto their radar, and ensure that MBP effectiveness and efficacy trials adhere to good practice in this area. Offering constructive commentary and clear guidance to authors will shape practice in this area

Conclusions

Strengthening methodological rigor in MBP research is important. Within this, developing empirical understanding on intervention integrity is a critical foundation for the rigorous and sustainable development of the science [3]. Critically, unless there is clear assessment and reporting of this, valid interpretation of research outcomes is difficult. Whether intervention integrity is actually a critical factor in enabling positive participant outcomes is an empirical question which as yet, has barely begun to be investigated. It is clear though, that in order for the field as a whole to bring the issue of intervention integrity onto the radar (both to ensure methodological rigour, and to question a potential research variable and mechanism), there needs to be consistency of assessment and reporting. This will create data within each individual trial, and a growing body of data which can be analysed across trials, thus enabling the integration of analysis of intervention integrity into MBP effectiveness and efficacy trials going forward. Furthermore, embedding assessment of intervention integrity into research trials is enormously helpful in informing the practical work of implementing evidenced-based MBPs into practice settings.

Current understandings on how best to assess intervention integrity in the MBP field are themselves preliminary and subject to evolution as evidence builds. The existing tools are though a platform for development. Implementing them in research contexts and refining them on the basis of evidence will be key to furthering this line of inquiry.

Conflicts of Interest

Rebecca Crane receives royalties for books she has authored on mindfulness-based programs. She is a trustee of the Mindfulness Network, a charity offering services to mindfulness-based teachers. She directs the Centre for Mindfulness Research and Practice at Bangor University which delivers professional training for mindfulness-based teachers.

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